

September 19, 2003

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By:

Sarah M. Barnett

PATENT

Customer No. 22,852

Attorney Docket No. 7579.0001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of:  
Graham Edmund KELLY

Reissue Serial No.: 09/602,191

U.S. Patent No. 5,830,887

Filed: June 22, 2000

For: HEALTH SUPPLEMENTS CONTAINING  
PHYTO-OESTROGENS, ANALOGUES  
OR METABOLITES THEREOF

)  
)  
) Group Art Unit: 1623  
)  
) Examiner: Patrick T. Lewis  
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MAIL STOP AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**NOTICE REGARDING RELATED LITIGATION**

Applicant hereby notifies the U.S. Patent and Trademark Office that a patent possibly related to the present application is involved in litigation. The present application, Serial No. 09/602,191, is a reissue application of U.S. Application Serial No. 08/338,567, originally filed as PCT/AU93/00230 on May 19, 1993, which entered the national stage on January 12, 1995, and which issued as U.S. Patent No. 5,830,887 on November 3, 1998. The patent in suit, U.S. Patent No. 6,562,380, issued from U.S. Application Serial No. 08/910,837 on May 13, 2003, and was originally filed on August 13, 1997, as a continuation of U.S. Application 08/338,567, described above. Application Serial Nos. 08/338, 567 and 08/910,837 are assigned to Novogen Pty. Ltd. ("Novogen").

**STATUS OF RELATED LITIGATION**

On June 3, 2003, Solae, L.L.C. ("Solae") filed a Complaint alleging that Archer Daniels Midland Company ("ADM") and Amerifit Nutrition, Inc. ("Amerifit") infringe at least one claim of

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U.S. Patent No. 6,562,380. The case, Civil Case No. 03-CV-732, was filed in U.S. District Court for the Eastern District of Missouri. The undersigned believes that Solae is the exclusive licensee of U.S. Patent No. 6,562,380 for products containing soy-derived isoflavones.

On June 23, 2003, ADM filed a Motion for extension of time to answer the Complaint until July 3, 2003. On June 26, 2003, the judge granted the Motion for extension of time to answer the complaint until July 3, 2003. On June 30, 2003, Amerifit filed a motion for extension of time to respond to the Complaint up to and including July 14, 2003. On July 3, 2003, ADM filed a motion to dismiss. On July 11, 2003, Amerifit filed a motion to dismiss. On August 11, 2003, Solae filed a response to the motions to dismiss. On August 14, 2003, Amerifit and ADM filed replies to Solae's response to the motions to dismiss. On August 26, 2003, Solae file a sur-reply to the motion to dismiss.

**REMARKS**

Further to this Notice of Related Litigation, the Applicant submits a copy of the Complaint and a copy of the docket for Civil Case No. 03-CV-732, as of September 5, 2003.

If there are any fees due with the filing of this Notice not already accounted for, please charge the fees to our Deposit Account No. 06-0916

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: September 19, 2003

By: Robert W. Mann  
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UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

FILED

SOLAE, L.L.C.

Plaintiff,

vs.

ARCHER DANIELS MIDLAND  
COMPANY

and

AMERIFIT NUTRITION, INC.

Defendants.

SERVE DEFENDANTS AT:

(for Archer Daniels Midland Co.)  
C T CORPORATION SYSTEM  
120 South Central Avenue  
Clayton, Missouri 63105

and

(for Amerifit Nutrition, Inc.)  
CORPORATION SERVICE COMPANY  
50 Weston Street  
Hartford, Connecticut 06120

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JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Solae, L.L.C. ("Solae" or "Plaintiff"), by its attorneys, for its Complaint against Archer Daniels Midland Company and Amerifit Nutrition, Inc. ("Defendants"), alleges and avers as follows:

## JURISDICTION AND VENUE

1. This is an action for patent infringement arising under Title 35 of the United States Code, Chapter 28, Section 271 and Chapter 29, Section 281, *et seq.*
2. Upon information and belief, Defendants have committed infringing acts in this district and are subject to personal jurisdiction in this district.
3. Jurisdiction is conferred on this Court pursuant to 28 U.S.C. §§1331, 1332 and/or 1338(a).
4. Venue is proper in this district pursuant to 28 U.S.C. §§1391(a), (b), (c), 28 U.S.C. §1400(b), and E.D.Mo. L.R. 2.07(B)(3) and (4).

## THE PARTIES

5. Plaintiff Solae, L.L.C. ("Solae" or "Plaintiff") is a Delaware limited liability corporation, having a principal place of business in St. Louis, Missouri.
6. Upon information and belief, defendant Archer Daniels Midland Company ("ADM") is a corporation organized under the law of Delaware, having its principal place of business at 4666 Faries Parkway, Decatur, Illinois 62526.
7. Upon information and belief, defendant Amerifit Nutrition, Inc. ("Amerifit") is a corporation organized under the law of Delaware, having its principal place of business at 166 Highland Park Drive, Bloomfield, Connecticut 06002.

## BACKGROUND

8. St. Louis-based Solae is a leader in the research, manufacturing and marketing of high-quality, soy-based ingredients and ingredient systems.
9. Isoflavones are bioactive chemicals found naturally in plants. Soy isoflavones exist in three main families: genistein, daidzein and glycitein. Four chemical forms of isoflavones known as aglucones, glycosides, malonyl conjugates, and acetyl conjugates are found within each family. Soybeans are the major food source of the naturally-occurring isoflavones genistein and daidzein.
10. In the production of commercial products such as soy protein concentrates, the focus has been to remove soy isoflavone compounds since they are associated with the bitter flavor of soybeans. In a conventional process for the production of a soy protein concentrate, extracted material containing soy isoflavones, is typically discarded. As a result, the extract from a conventional process is an inexpensive and desirable source of soy isoflavones.
11. Recent clinical research suggests that isoflavones contained in vegetable protein materials such as soybeans, are bioactive compounds that may provide various health benefits, including the reduction of cardiovascular risk factors, the amelioration of conditions caused by reduced levels of endogenous estrogen in women (e.g., menopause or premenstrual syndrome), and the inhibition of certain human cancer cells (e.g., breast and prostate cancer cells).

12. U.S. Patent No. 5,990,291, issued November 23, 1999 (Reexamination Certificate 5,990,291 C1, issued August 28, 2001) (copy attached as Exhibit A) ("the '291 patent") entitled "Recovery of Isoflavones from Soy Molasses," names Doyle Waggle and Barbara Bryan as inventors and lists as assignee Protein Technologies International, Inc. ("PTI").
13. U.S. Patent No. 6,562,380 issued May 13, 2003 (copy attached as Exhibit B) ("the '380 patent") entitled "Methods for Treating or Reducing Predisposition to Breast Cancer, Pre-Menstrual Syndrome or Symptoms Associated with Menopause by Administration of Phyto-Estrogen," names Graham Kelly as inventor and lists on its face Novogen Research Pty. Limited (New South Wales, Australia) as assignee.
14. On or about March 28, 2003, PTI was renamed and reincorporated as Solae. Solae is the sole and exclusive licensee of the '380 patent for products containing soy-derived isoflavones.
15. Upon information and belief, ADM manufactures and markets a product that infringes at least one claim of the '291 patent which product is known as Novasoy® ("Novasoy") and is a powdered compound extracted from soybeans containing naturally-occurring isoflavones.
16. Upon information and belief, ADM's Novasoy contains at least the soy isoflavones daidzein, genistein, and glycitein, their glucosides, and acetyl and malonyl esters.
17. Upon information and belief, ADM's Novasoy isoflavone material is marketed and sold by ADM in this district and throughout the United States.

18. Upon information and belief, ADM's Novasoy isoflavone material is marketed and sold by ADM to manufacturers for incorporation into health and/or dietary supplements that infringe at least one claim of the '380 patent and are marketed and sold in this district and throughout the United States.
19. Upon information and belief, Amerifit manufactures and markets a product that infringes at least one claim of the '291 patent and at least one claim of the '380 patent, which product is known as Estroven<sup>®</sup> ("Estroven") and is a health supplement containing Novasoy isoflavone material provided by ADM.
20. Upon information and belief, Amerifit's Estroven contains at least the soy isoflavones daidzein, genistein, and glycitein, their glucosides, and acetyl and malonyl esters.
21. Upon information and belief, Amerifit's Estroven is marketed and sold by Amerifit in this district and throughout the United States for alleviating symptoms associated with menopause.

#### **FIRST CAUSE OF ACTION**

#### **PATENT INFRINGEMENT**

22. Solae here repeats and incorporates by reference all the allegations of paragraphs 1 through 21 above.
23. By assignment from all joint inventors, PTI was the owner of the '291 patent and sole and exclusive licensee of the '380 patent, and, upon formation of Solae, Solae became

the owner of PTI's intellectual property rights relating to soy isoflavones, including those relating to the '291 and the '380 patents.

24. Upon information and belief, ADM has directly and/or contributorily infringed at least one claim of the '291 patent and at least one claim of the '380 patent in connection with making, using, offering to sell, selling, and/or importation of Novasoy. ADM will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.
25. Upon information and belief, ADM has knowingly induced others to infringe at least one claim of the '291 patent and at least one claim of the '380 patent in connection with making, using, offering to sell, selling, and/or importation of Novasoy. ADM will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.
26. Upon information and belief, ADM's infringement of the '291 and the '380 patents is knowing and willful.
27. Upon information and belief, Amerifit has directly and contributorily infringed at least one claim of the '291 patent and at least one claim of the '380 patent in connection with making, using, offering to sell, selling, and/or importation of Estroven. Amerifit will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.
28. Upon information and belief, Amerifit has knowingly induced others to infringe at least one claim of the '291 patent and at least one claim of the '380 patent in



connection with making and/or using of Estroven. Amerifit will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.

29. Upon information and belief, Amerifit's infringement of the '291 and the '380 patents is knowing and willful.

#### **REQUEST FOR RELIEF**

WHEREFORE, Solae prays that this Court enter judgment in its favor against the Defendants and grant the following relief:

- A. Permanently enjoin Defendants, their agents, successors and assigns and all persons acting on their behalf or within their control, from making, using, selling, or offering to sell, importing or otherwise engaging in acts of infringement of the '291 and the '380 patents;
- B. Award Plaintiff damages caused by Defendants' patent infringement as determined by the jury in this action;
- C. Award treble damages pursuant to 35 U.S.C. §284;
- D. Enter an order declaring this an exceptional case and awarding Plaintiff interest, costs and disbursements in this action, including reasonable attorneys' fees pursuant to 35 U.S.C. §285; and
- E. Award Plaintiff such further relief as the Court may deem just and proper.

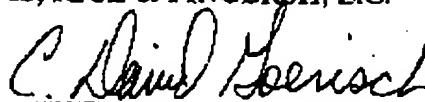
**DEMAND FOR A JURY TRIAL**

Plaintiff hereby demands trial by jury of all issues so triable in this action.

DATED: June 3, 2003

LEWIS, RICE & FINGERSH, L.C.

By:



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